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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,275	08/30/2001	John David Bentley	50179-081	9040

7590 08/19/2004

McDermott Will & Emery
600 13th Street NW
Washington, DC 20005-3096

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,275	BENTLEY ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,21,23,24,26,31,34,35,37,39-41 and 43-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 21, 23-24, 26,31,34-35,37,39-41, 43-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/7/04 has been entered.

Claims 1, 21, 23-24, 26, 31, 34-35, 39-41, and 43-49 are pending.

Claim Objections

Claims 48 and 49 are objected to because of the following informalities: These claims lack a terminal period (“.”). Appropriate correction is required.

Drawings

Applicant's comments concerning the drawing are noted. However, the examiner has no knowledge as to why there are marks on the PTO-948 in applicant's possession. The examiner's copy of the PTO-948 contains no such marks (see attached). To the best of the examiner's knowledge the objections to Figures 3-8, 10, and 11 are still pertinent. Again, applicant's renumbering of the subparts does not correspond with the numbering within the specification.

Claim Rejections - 35 USC § 112

Claims 1, 21, 23-24, 26, 31, 34-35, 39-41, and 43-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 21 have been amended to recite a list of particular ligands. There does not appear to be any contemplation or disclosure in the specification for methods which identify compounds which modulate binding of the particular set of compounds to the IGF-1R receptor now recited in the claims. Disclosure that these compounds are known to bind to the IGF-1R receptor is not basis for this claim limitation.

The examiner is unable to find basis in the specification for “modulates signal transduction by binding.” Note that this is not synonymous with the originally filed claim language of “modulate an activity mediated by the molecule.” Pages 17-18 discuss antagonists and not general modulators. Likewise, the subject matter of claim 34 is broader than the disclosure here.

The examiner is unable to find basis in the specification for step (B) “selecting and obtaining” of claims 1, 21, and 49.

The claims as presently written differ significantly from the originally filed claims. Applicant is requested to point with particularity to the specification by page and line number to show basis or contemplation for each of the claims, particularly the

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selecting, obtaining (particularly obtaining after outputting as in claim 24, for example), and testing steps.

Claims 1, 21, 23-24, 26, 31, 34-35, 39-41, and 43-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This enablement rejection is maintained with respect to stereochemical complementarity and subsets of amino acids as set forth in the prior Office action and as discussed below.

Stereochemical complementarity does not appear to have an art understood definition and applicant's specification and arguments do not provide one. As such, one would be unable to practice the invention as claimed because one of ordinary skill in the art is not reasonably guided as to what to do. Note further with the selection of step (B) no criteria are provided. Applicant argues on page 14 of the response that the "concept of 'selecting' relates to a choice being made with respect to the best or most suitable compounds in terms of stereochemical complementarity to the molecule of present interest." This concept or what applicant intended is not set forth in the claims or specification. Applicant has provided a list of references but not the references themselves. In addition, no art understood or limiting definition of what defines "stereochemical complementarity" such that one would know when such a limitation has been met.

With respect to the “subsets,” the specification does not provide guidance on which subsets to use. That is, the model based on amino acids 1-462 is used and compounds are designed to bind to particular regions.

Claims 21, 23-24, and 26 are directed to a computer-assisted method for identifying potential compounds. Applicant is again requested to explain what a criteria data set must include and how it is generated. The specification provides no guidance on how to compare this data set to a computer database. Applicant has argued it is clear from the claim language but has not provided an explanation. The specification provides no guidelines or criteria by which selection must be made. How “structurally similar” must the chemical structure in the database be to the criteria data set? What degree of similarity is sufficient?

With respect to claims 39-40, the specification provides no guidance on how to modify any compound found by the method of claim 1 to result in the properties desired and recited in claim 39-40.

Claims 1, 21, 23-24, 26, 30-32, and 34-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites “which are structurally similar.” It is unknown what degree of similarity is required to meet this limitation.

Claims 39-40 are still confusing referring to Figure 2. Figure 2 does not clearly show the amino acid residues intended to meet the limitation of “at the surface of the

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molecule” or “in the region of the interface between the L1 domain and the Cys-rich domain.” It is not known what particular amino acid regions were intended.

With respect to claims 24, 26, 44-45, it is not known what the increase or decrease in signal transduction is in comparison to.

Claim 41 lacks antecedent basis for “one or more subsets” in claim 1.

Conclusion

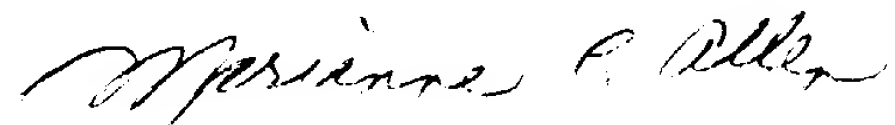
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO’s Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO’s Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO’s PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



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3/16/04

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Primary Examiner
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